The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Clinical Trial Planning Milestone Checklist

To be completed by the applicant
Date:

Title of study:

Principal Investigator:

Institution:

Applicant Contact: Email Phone

Form completed by:

Does the Applicant have a Prior NIAMS-funded U34/R34 (yes/no)?
Proposed date of submission of the U01 application (see deadlines below):

Note: If the budget is $500,000 or greater in direct costs in any given year, a separate Letter of Request (LOR) must be submitted by the appropriate deadline (10 weeks prior to the application due date). No exceptions.

Proposed Clinical Trial Budget (total costs all years – direct and indirect costs):

Proposed Direct Costs only per Year:

Year 1:	**Year 2:**	**Year 3:**	**Year 4:**	**Year 5:**

Due dates for a U01 application, U34 Waiver Requests, and/or Letters of Requests (applications with budgets of $500,000 or greater in direct costs in any given year)

U01 Application Due Date	**Letter of Request (LOR) Request Due Date (required 10-weeks prior to the application due date)**
March 27, 2018	February 13, 2018 *(6-weeks only for this due date)*
July 2, 2018	April 23, 2018
November 2, 2018	August 24, 2018
March 4, 2019	December 31, 2018
July 2, 2019	April 23, 2019
November 4, 2019	August 26, 2019
March 3, 2020	December 24, 2020

July 2, 2020	April 23, 2020
November 3, 2020	August 25, 2020

Instructions: The applicant should indicate a status by marking an "X" under the appropriate status heading for each planning activity with additional comment (s) to justify any item(s) that are not complete at the time the checklist is submitted to the NIAMS.

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Study protocol						
Budget proposal for U01 application						
Identification and qualifications of clinical trial sites, pharmacies and laboratories						
Investigator Brochure (IB) or equivalent						
MOOP						
Data and safety monitoring plan						
Finalize plans to obtain intervention related products (drugs, placebo, device)						

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Develop Clinical Trial Agreement (CTA) and/or Cooperative Research and Development Agreement (CRADA)						
Develop template informed consent (and assent form, if applicable)						
Develop case report forms						
Program database						
Establish data collection system for primary and/or remote sites						
Submit/obtain approval for IND/IDE						
Develop and plan materials for training and site initiation						
Initiate IRB approval/request applicable waivers (e.g., HIPAA)						

Planning Activity	**Status**				***Comments** (please include additional detail regarding the status of the activity including any anticipated dates of completion if the activity is not yet complete)	**NIAMS Internal Use Only**
	Completed (please provide dates of completion)	In process *	Not started *	Not applicable *		
Documentation of adequate co-funding, if applicable and necessary for completion of the trial						
Other:						
Other:						
Other:						
Other:						

NIAMS Staff Comments (internal use only):